REMARKS

Applicant respectfully requests reconsideration of the present Application in view of the foregoing amendments and in view of the arguments which follow:

A. 35 U.S.C. § 112 (2d paragraph)

The examiner has rejected all claims under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

In response, Applicant has submitted new claims 19 through 45 which overcome the objections as to form. Specifically, the new claims further define "tonicity" to mean "a tonicity which is sufficiently hypertonic to minimize cooling injury." The phrase "similar relative proportion," used in original claim 11, corresponding new claim 29, has been deleted and replaced with alternate language. Finally, the lack of an antecedent basis for the phrase "the tonicity of the medium" has been corrected in new claim 19.

B. Nonstatutory Double Patenting

In response to this objection, Applicant has abandoned U.S. Patent No. 09/771,221 without traverse.

C. 35 U.S.C. § 103(a)

The examiner has rejected all original claims 1-18 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,693,534 and U.S. Patent No. 6,274,303. The examiner contends that the cited patents "teach adding cryoprotectants to a medium comprising cells and cooling processes as well as vitrification." The examiner further contends that it is well known in the art that the "process steps of the claims [of the present invention] require tonicity." These contentions are apparently based upon the '534 patent's disclosure of adding living cells to a cryopreservative solution until the cells are equilibrated, and the '303 patent's disclosure of rapid internal cooling of living cells, using cryopreservative agents to reduce ice formation and mechanical injury, and rewarming the living cells with an inert fluid. The examiner's contentions are incorrect. As demonstrated by Applicant's new set of claims, Applicant's invention requires a "preservation medium

having a tonicity which is sufficiently hypertonic to minimize cooling injury." (See new claim 19.) Neither cited patent mentions "tonicity." Further, even if the existence of the phenomena of tonicity were implied, neither patent discloses the significance of preparing and using a "preservation medium having a tonicity which is sufficiently hypertonic to minimize cooling injury."

The technology disclosed in the cited patents is directed solely to reducing ice formation and resulting mechanical damage to a living cell, and the patents do not teach the significance of the hypertonicity of the preservation medium. In fact, the prior art teaches away from the present invention. Previously, it was thought that a preservation medium which was hypertonic exacerbated the adverse effects of cooling or chilling injury. (See U.S. Patent No. 5,723,282.) To the contrary, the present invention teaches that a preservation medium which is hypertonic makes cooling injury less severe. (See, Applicant's Application, page 10, lines 11 through 13.) The fact that the prior art "teaches away" from the claimed invention is a significant factor to be considered in determining obviousness (M.P.E.P. § 2145).

Finally, the examiner states that vitrification is a well known procedure and is known to "reduce cooling injury." As the term "cooling injury" or "chilling injury" is defined in the specification, the examiner's statement is incorrect. The specification distinguishes "cooling injury" from "freezing injury" and defines "cooling injury" as being either thermal shock or chilling injury, where thermal shock and chilling injury are "caused by exposure to low temperatures per se." (See, Applicant's Application, page 2, lines 6 through 7.) Vitrification is only known to inhibit "freezing injury," but it has no protective effect on "cooling injury" as defined in the patent application. Again, Applicant's invention "inhibits cooling injury," rather than "freezing injury." Accordingly, the examiner's observation is not material to the present invention.

Applicant respectfully submits that the claims are not obvious in light of the prior art cited by the examiner.

Accordingly, Applicant requests that the present application be allowed.

Respectfully submitted,

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By

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION:

1. **Entire paragraph beginning on line 9 and continuing through line 12 of page 5.**

A further embodiment is the use of hypertonic medium to reduce both cryoprotectant toxicity and chilling injury, wherein the hypertonic medium is added and removed in a manner that simulates the effects of both freezing and thawing. In a further embodiment the hypertonic medium prevents cooling injury at subzero temperatures.

2. **Entire paragraph beginning on line 26 and continuing through line 29 of page 5.**

Figure 1 shows the viability of ~~frozen~~ rabbit renal cortical slices subjected to simulated freezing in either DMSO (D) or Veg (V) at various concentrations. Viability is measured by tissue K/Na ratios after restoration of active metabolism. Each bar represents 6-12 individual slices.

IN THE CLAIMS:

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